

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
21 May 2004 (21.05.2004)

PCT

(10) International Publication Number
WO 2004/041332 A1

(51) International Patent Classification⁷: **A61M 5/32**

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(21) International Application Number:
PCT/IT2002/000696

(22) International Filing Date:
4 November 2002 (04.11.2002)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicants and

(72) Inventors: **RESTELLI, Sergio** [IT/IT]; Via Quarto Peperino, 333 B, I-00100 Roma (IT). **RIGHI, Nardino** [IT/IT]; Via Cavour, 7, I-20047 Brugherio (IT). **ROSSI, Roberto** [IT/IT]; Via delle Ande, 10, I-20151 Milano (IT).

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

(74) Agents: **PETRUZZIELLO, Aldo** et al.; Racheli & C. S.p.A., Viale San Michele del Carso, 4, I-20144 Milano (IT).

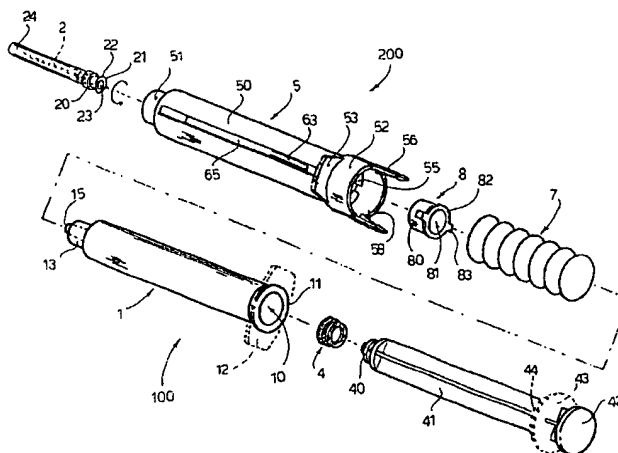
Published:

— with international search report

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SET OF COMPONENTS FOR MAKING A SYRINGE INTO A DISPOSABLE AUTOMATIC SAFETY SYRINGE AND RELATIVE DISPOSABLE AUTOMATIC SAFETY SYRINGE



(57) Abstract: In a syringe (100) comprising a syringe body (1) hollow on the inside, a plunger (4) slidable inside the syringe body (1) and provided at the rear with a manually operable shaft (41), and an injection needle (2) engageable to the front end (13) of the syringe body (1) by means of a needle-carrier (20), there is applied a set of components comprising a sleeve (5) mounted slidably over the syringe body (1) to pass from a retracted position of use of the syringe to a forward position of safety in which it covers the needle (2), spring means (7) disposed under compression between the sleeve (5) and the syringe body (1) and guide means (60) disposed in the sleeve and cooperating with complementary guide means (83) disposed on a guide element (80) made integral with the syringe body (1) to guide the axial movement of the sleeve (5) with respect to the syringe body.

WO 2004/041332 A1

**SET OF COMPONENTS FOR MAKING A SYRINGE INTO A DISPOSABLE
AUTOMATIC SAFETY SYRINGE AND RELATIVE DISPOSABLE
AUTOMATIC SAFETY SYRINGE**

5 DESCRIPTION

The present invention refers to a set of components that can be applied to a conventional syringe to make it into a disposable automatic safety syringe. The present invention also refers to a disposable automatic safety syringe obtained from
10 said set of components.

As is known, a syringe generally comprises a cylindrical body open at the rear to receive a plunger. A needle hollow on the inside is mounted at the head of the syringe body. On retraction of the plunger the liquid contained in a vial is drawn into the
15 syringe body through the needle. On pressing on the plunger the liquid contained in the syringe body is injected, through the needle, into the patient's body.

Because of health regulations and to avoid transmission of infectious diseases, syringes must generally be used only once and then discarded. For this reason, there is
20 a growing market demand for disposable syringes able to prevent further use.

Moreover, syringes generally present drawbacks from the point of view of safety. In fact, once the syringe has been used, the needle remains exposed at the head of the syringe body, with the risk of injuries and accidental needle sticks.
25

Patent application PCT WO 99/37345 describes a disposable safety syringe which has a needle covering sleeve mounted axially on the body of the syringe and slidable from a retracted position in which it leaves the needle exposed to allow injection, to a forward position in which it completely covers the needle, preventing re-use of the
30 syringe and acting as a protection against accidental needle sticks.

Once the injection has been performed, the sleeve is automatically brought into the extracted safety position, by means of an automatic mechanism and without any intervention by the user. However, this solution presents a certain complexity due to

the presence of various additional elements for operation of the automatic mechanism. Furthermore, the telescopic movement of the sleeve on the syringe body is not guided, with the result of possible jamming and malfunctioning of the safety device of the syringe.

5

The object of the present invention is to eliminate the drawbacks of the prior art, providing a set of components that is extremely versatile and suitable to be applied to various types of conventional syringes to make them into disposable automatic safety syringes.

10

Another object of the present invention is to provide such a set of components that is economical, simple to make and simple to assemble.

Another object of the present invention is to provide such a disposable automatic safety syringe that is able to prevent both further attempts at use and accidental injury after use thereof.

15

These objects are achieved in accordance with the invention with the set of components according to appended independent claim 1 and with the disposable automatic safety syringe according to appended independent claim 13.

20

Advantageous embodiments of the invention are apparent from the dependent claims.

According to the invention a set of components is applied to a syringe to make it into a disposable automatic safety syringe.

25

The syringe comprises a syringe body hollow on the inside and open at the front and the rear, a plunger that can slide inside the syringe body with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, and an injection needle supported by a needle-carrying support engageable to the fore end of the syringe body. The plunger is provided at the rear with a shaft that can be operated manually and brought out of the syringe body through the rear end thereof.

30

The set of components comprises a sleeve, spring means and a guide element.

The sleeve is slidably mounted over the syringe body, to pass from a retracted position of use of the syringe to a forward position of safety, in which it covers the needle.

5

The spring means are disposed under compression between the sleeve and the syringe body to urge the axial movement of the sleeve into the forward position of safety with respect to the syringe body.

10 The guide element is able to be mounted integrally to the syringe body. Said guide element comprises guide means cooperating with complementary guide means provided in the sleeve to guide the axial movement of the sleeve with respect to the syringe body.

15 The sleeve is locked in the position of use by means of locking means, in reciprocal engagement, provided in the rear part of the sleeve and of the syringe body.

In the rear part of the shaft, on the other hand, operating means are provided to release the locking means, when the plunger reaches the end of the injection stroke, so as to
20 allow the action of the spring means which automatically generate the axial movement of the sleeve with respect to the syringe body. Said operating means can be formed integrally with the shaft, or they can form part of the set of components and therefore they can be applied to the shaft.

25 The advantages of the set of components according to the invention are obvious.

In fact such a set of components, including only three additional elements, that is to say the sleeve, the spring means and the guide means, proves extremely cheap and simple to make, and can be applied in a simple and convenient manner to a
30 conventional syringe so as to make it into a disposable automatic safety syringe.

The disposable automatic safety syringe obtained with the set of components according to the invention proves practical for the user and meets the objects of the present invention.

In fact, once the injection has been completed, the sleeve is automatically guided in its telescopic movement on the syringe body, without any intervention by the user, so as to cover the needle. In this manner the needle is in a position of safety and thus
5 accidental needle sticks and any attempts at reuse of the syringe are prevented.

Further characteristics of the invention will be made clearer by the detailed description that follows, referring to purely exemplary and therefore non limiting embodiments thereof, illustrated in the appended drawings, wherein:

10

Figure 1 is an exploded axonometric view illustrating the set of components according to the invention and a conventional syringe;

15

Figure 2 is a side view of a sleeve forming part of the set of components of Figure 1;

Figure 3 is an axial sectional view of the sleeve, taken along the sectional plane III-III of Figure 2;

20

Figure 4 is a cross sectional view of the sleeve taken along the sectional plane IV-IV of Figure 3;

25

Figure 5 is an axial sectional view of the syringe of Figure 1, assembled and with the set of components applied, wherein the plunger of the syringe is near its forward end of stroke;

Figure 6 is a view partially in axial section of the syringe assembled with the set of components, wherein the needle is in the safety position, protected by the sleeve;

30

Figure 6a is an axial sectional view of an enlarged detail of Figure 6;

Figure 7 is an axonometric view of the syringe assembled with the set of components, ready for use;

Figure 8 is an axonometric view of the syringe assembled with the set of components, in the safety position;

Figure 9 is a variant embodiment of the invention, illustrating in an axonometric exploded view a syringe body and a guiding and supporting needle element of the set of components according to the invention;

Figure 10 is an axial sectional view, enlarged and broken off, illustrating the guiding and supporting needle element of Figure 9 mounted at the head of the syringe body.

10

The set of components according to the invention which can be applied to a syringe to make it into a disposable automatic safety syringe is described with the aid of the figures.

15 With reference for now in particular to Figure 1, a conventional syringe, indicated as a whole with reference numeral 100 and a set of components indicated as a whole with reference numeral 200, is illustrated.

20 The syringe 100 is a syringe that can commonly be found on the market and comprises a syringe body 1, an injection needle 2, a plunger 4 and a shaft 41.

The syringe body 1 is cylindrical, hollow on the inside, and defines a cylindrical chamber 10. The rear end of the body 1 is open toward the outside and has an annular collar 11 which protrudes radially outward. Two tongues or flanges 12 (shown with a dashed line) which protrude radially outward in diametrically opposite positions can be provided on the annular rim 11, to define gripping means for the user's fingers.

25

The front end of the body 1 ends in a head 13, open towards the outside, with a substantially cylindrical or frusto-conical shape, with a smaller diameter than the body

30 1.

As shown better in Figures 5 and 6, the head 13 of the syringe body can consist of a threaded connector known as a Luer cone. The Luer cone head 13 has an inner thread 14 and a cylindrical or frusto-conical tang 15 disposed axially therein and having a

smaller diameter than that of the head 13, so as to leave an annular space between the outer surface of the tang 15 and the inner surface of the head 13.

Returning to Figure 1, the injection needle 2 is supported by a needle-carrying support
5 20 with a cylindrical or truncated conical shape, hollow on the inside, having an axial chamber 23 able to receive the tang 15 of the head 13 of the syringe body. The support 20 of the needle has at its free end a collar 21 with two tongues 22 protruding radially in diametrically opposite positions. The tongues 22 can be replaced by an outer thread able to engage in the inner thread 14 of the head 13 of the syringe body. A needle cap
10 24 engages with the support 20 to cover the needle 2.

The plunger 4 can slide with a tight seal in the chamber 10 of the syringe body 1. The plunger 4 is mounted on the head 40 of the shaft 41 having a cross-shaped cross section. The shaft 41 ends at the rear in a disc-shaped flange 42 which provides an
15 abutment surface for the user's finger during injection.

Near the rear flange 42, around the shaft 41, an operating crown 43 (shown with a dashed line) which has a tapered front side surface 44 can be provided. The operating crown 43 can be made in a single body with the shaft 41 or with the rear flange 42 of
20 the shaft 41.

In the case of the shaft 41 of the conventional syringe 100 not having the operating crown 43, said operating crown 43 can be made as a separate element forming part of the set of components 200 and can thus be assembled with the shaft 41, as shown in
25 the figures.

The set of components 200 comprises a guide element 8, a sleeve 5, a spring 7 and optionally an operating crown 43.

30 The guide element 8 takes the form of a cylinder 80 hollow on the inside, having an axial cavity 81 with substantially the same outside diameter as the head of the Luer cone 13 of the syringe body to be able to applied thereon by pressing. The guide element 8 has an annular rim 82 protruding radially outward. Two nibs 83 protruding

radially outward in diametrically opposite positions are provided on the annular rim 82.

As also shown in Figures 2 and 3, according to the invention the set of components 200 comprises a safety device of the syringe, designated with reference numeral 5 and taking the form of a sleeve with a substantially cylindrical body 50, hollow on the inside, having an axial chamber 54 open at the front and rear. The sleeve 5 has a front part 51 with a smaller diameter and a rear part 52 with a larger diameter than the central part 50 of the body. The inside diameter of the central part 50 of the body of the sleeve is slightly greater than the outside diameter of the syringe body 1, so that the sleeve 5 can slide axially on the syringe body.

Two radially outward protruding stiff tongues or flanges 53 are provided between the central part 50 and the rear part 52 of the body of the sleeve, to generate a resting surface for the user's fingers. Again between the central part 50 and the rear part 52 of the body of the sleeve, an annular abutment surface 55 which protrudes radially inward is generated on the inside.

Two flexible longitudinal tongues 56 disposed in diametrically opposite positions are provided in the rear part 52 of the body of the sleeve. Each tongue 56 is defined by two parallel longitudinal notches 57 (Fig. 3) on the rear part 52 of the body of the sleeve, so as to be able to bend outward with respect to the body of the sleeve.

Each longitudinal tongue 56 has an inwardly protruding part 58 disposed substantially in a central position. Each protrusion 58 has a tapered rear portion 58' and a radial front abutment surface 58''.

Furthermore, each tongue 56 protrudes rearward with respect to the rear edge of the rear part 52 of the sleeve and has in its rear end an inside surface 59, substantially tapered, which forms an extension of the tapered surface 58' of the protrusions 58. The tapered parts 59, 58' of the tongues 56 are able to cooperate with the tapered surface 44 of the operating crown 43 of the shaft 41.

The body 50 of the sleeve 5 has two longitudinal protrusions 65 disposed in diametrically opposite positions. As shown in Figure 4, two longitudinal guide channels 60 are formed in the inner surface of the longitudinal protrusions 65, able to receive the nibs 83 of the guide element. As shown in Figure 6, each longitudinal
5 channel 60 has a front abutment and an end of stroke surface 61.

In the rear part of each longitudinal channel 60 there extend two flexible tongues 63, 67, longitudinal and opposite each other, defined by longitudinal notches 66 made in the protruding part 65 of the body of the sleeve. The two tongues 63 and 67 are
10 inclined slightly inward and end in respective abutment surfaces 64 and 62, opposite each other, which define a locking seat able to lock the nibs 83 of the guide element 80.

Lastly, the set of components 200 comprises the spiral spring 7, intended to be housed
15 in the rear part 52 of the body of the sleeve and able to allow the syringe body 1 to pass therein.

Assembly of the set of components 200 on the syringe 100 is illustrated below, purely by way of example, with the aid of Figures 5, 6 and 6a.
20

The plunger 4 is mounted in the head 40 of the shaft 41 and inserted in the syringe body 1. The spring is inserted from the front onto the syringe body 1, until one end of the spring 7 abuts against the annular rim 11 of the syringe body. The guide element 8 is applied on the head 13 of the syringe body. The support 20 of the needle 2 is
25 screwed into the head 13 of the syringe body.

At this point the sleeve 5 is inserted from its rear onto the syringe body so that the nibs 83 of the guide element 8 slide in the longitudinal channels 60 of the central part 50 of the body of the sleeve. At the same time the longitudinal tongues 56 of the rear part 52
30 of the body of the sleeve bend outward, until the annular rim 11 of the syringe body passes the protrusions 58 and following the elastic return of the tongues 56, the annular rim 11 of the syringe body is retained by the front abutment surface 58'' of the protrusions 58 of the tongues.

In this situation, the nibs 83 of the guide device 8 abut against the respective front abutment surfaces 61 of the longitudinal channels 60 of the sleeve and the rear rim 11 of the syringe body is retained by the protrusions 58 of the longitudinal tongues 56 of the rear part of the sleeve. In this manner the sleeve 5 is made integral with the syringe
5 body and any axial movement of the sleeve 5 with respect to the syringe body 1 is prevented. It should further be noted that in this situation the spring 7 is compressed with one end abutting against the annular rim 11 of the syringe body and the other end abutting against the annular abutment surface 55 of the rear part of the sleeve.

- 10 Operation of the syringe 100 provided with the safety accessories 200 according to the invention is described hereunder with reference to Figures 5, 6, 6a, 7 and 8.

As shown in figures 5 and 7, when the plunger 4 reaches the end of the injection stroke inside the chamber of the syringe body, the operating crown 43 of the shaft 41
15 is in contact with the longitudinal flexible tongues 56 of the rear part of the sleeve. To be precise, the tapered surface 44 of the operating crown of the shaft cooperates with the tapered surface 59 of the tongues of the rear part of the sleeve and with the tapered surface 58' of the protrusions 58, causing outward bending of said tongues 56.

- 20 As a result, the rear edge 11 of the syringe body is released from the protrusions 58 of the tongues 56. Consequently, axial movement of the sleeve 5 with respect to the syringe body 1 is no longer prevented. Thus through the action of the spring 7, which is released, the sleeve 5 moves axially forward with respect to the syringe body 1 and/or the syringe body 1 moves axially rearward with respect to the sleeve 5. It
25 should be noted that the movement of the sleeve 5 occurs automatically through the action of the spring 7 without any need for manual intervention by the user.

During said axial movement, the sleeve 5 is guided by the nibs 83 of the guide device 8 which slide in the longitudinal channels 60 of the sleeve. When the nibs 83 of the
30 guide device reach the rear part of the respective channels 60, said nibs 83 push the first elastic tongues 63, which bend outward.

At the end of the stroke of the sleeve 5, as shown in Figures 6, 6a and 8, the nibs 83 of the guide device 8 abut against the front abutment surface 62 of the second tongues 67

of the sleeve. In this situation the needle 2 is protected by the sleeve 5, which is in the forward position of safety. It should be noted that in this situation the elastic tongues 63 of the sleeve return elastically to their initial configuration and thus the nibs 83 of the guide element 80 are locked between the rear abutment surface 64 of the first
5 tongues 63 and the front abutment surface 62 of the second tongues 67. In this manner any axial movement of the sleeve with respect to the syringe body is prevented.

It should be noted that in the present invention a syringe of the conventional type, composed of a body 1, the plunger 4 with the piston 41 thereof and the needle 2 with
10 the needle-carrying support 20 thereof, is made into a safety syringe through the use of only three additional elements forming part of the set 200, that is to say the sleeve 5, the spring 7 and the guide device 8. Furthermore, the set of components 200 can optionally also comprise the operating crown 43 to be applied to the piston shaft 41, in the event of said operating crown 43 not being made integrally or in a single body
15 with the stem 41.

In Figures 9 and 10 a variant embodiment of the invention is presented, used in the case of the syringe body not having a Luer cone in its head, but simply a tang 115 with a small diameter.

20 In this case the guide element 108 will be made like a Luer cone to be able to support the needle 2. The needle guiding and supporting element 108 comprises a body consisting of a substantially cylindrical element 180 disposed on a rear flange 182. The cylindrical element 180 has on its inner surface a thread 185 able to engage with
25 the threads 22 of the support 20. The rear flange 182 has an axial through hole 181 able to receive the tang 115 of the head of the syringe body 1.

As shown in Figure 10, when the tang 115 of the head of the syringe body 1 is inserted in the hole 181 of the rear flange of the guide element, it is disposed coaxially
30 with respect to the cylindrical element 180, forming a Luer cone. Thus, the cylindrical element 180 and the tang 115 are spaced apart from each other so as to leave an annular space 187 able to receive the support 20 of the needle 2.

Two nibs 83 substantially the same as those already described with reference to the guide element 8 of the first embodiment protrude radially outward from the rear flange 182, in diametrically opposite positions.

- 5 In the present description the nibs 83 which slide in the channels 60 of the sleeve have been made in the guide device 8. However, said nibs 83 can be made integral with the syringe body 1 or with the head of the syringe body, or alternatively they can be provided in a separate needle-carrying device suitable to be applied to the head of the syringe body.

10

Numerous variations and modifications of detail within the reach of a person skilled in the art can be made to the present embodiment of the invention, without thereby departing from the scope of the invention, expressed in the appended claims.

CLAIMS

1. A set of components (200) for making a syringe (100) into a disposable safety syringe, said syringe comprising:
- 5 - a syringe body (1) hollow on the inside and open at the front and rear,
 - a plunger (4) slidable inside the syringe body (1) with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger (4) being provided at the rear with a shaft (41) that can be operated manually and brought out of the syringe body through the rear end (42) thereof, and
- 10 - an injection needle (2) supported by a needle-carrying support (20) engageable to the front end (13; 115) of the syringe body (1),
 characterised in that said set of components (200) comprises:
- a sleeve (5) slidably mounted on said syringe body (1) to pass from a retracted position of use of the syringe to a forward position of safety, wherein it covers said
- 15 needle (2),
 - spring means (7) disposed under compression between said sleeve (5) and said syringe body (1) to urge the axial movement of the sleeve (5) with respect to the syringe body, and
 - a guide element (8; 108) able to be made integral with the syringe body (1) and
- 20 comprising guide means (83) cooperating with complementary guide means (60) formed in said sleeve (5) to guide the axial movement of the sleeve (5) with respect to the syringe body,
 there further being provided:
- locking means (56, 58, 11) provided in the rear part of the sleeve (5) and in the rear
- 25 part of the syringe body (1), in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of the spring means, and
 - operating means (43) disposed in said shaft (41) to release said locking means (56, 58) when the plunger (4) reaches the end of the injection stroke, so as to allow axial movement of the sleeve in the safety position, thanks to the action of the spring
- 30 means.
2. A set (200) according to claim 1, characterised in that said guide means of the sleeve (5) comprise a pair of longitudinal channels (60) disposed in diametrically opposite positions in the central part of said sleeve and said guide means of the guide

element (8; 108) comprise a pair of teeth or nibs (83) disposed in diametrically opposite positions able to engage in a sliding coupling relationship in the respective longitudinal channels (60) of the sleeve.

- 5 3. A set according to claim 1 or 2 characterised in that the head (13) of said syringe body consists of a Luer cone and said guide element (8) has the form of an internally hollow cylindrical tang able to be applied on the head (13) of the syringe body.
- 10 4. A set according to claim 1 or 2, characterised in that the head (115) of said syringe body consists of a tang (115) with a small diameter and said guide element (108) has the form of a Luer cone having a through hole (181) axially to receive said tang (115) of the head of the syringe body.
- 15 5. A set according to any one of claims 2 to 4, characterised in that two longitudinal protrusions (65) wherein said longitudinal guide channels (60) are defined, are formed in diametrically opposite positions in said sleeve (5).
- 20 6. A set according to any one of the preceding claims, characterised in that locking means (63, 67) able to lock it to the syringe body when it is in its forward safety position are formed in said sleeve.
- 25 7. A set according to claim 6, characterised in that said sleeve locking means are a pair of opposite facing tongues (63, 67) disposed in each longitudinal channel (60) and having respective opposite facing abutment surfaces (64, 62) able to lock said nibs (83) of the guide element (8; 108) integral with the syringe body, to avoid axial movement of the syringe body, when the sleeve is in the forward safety position.
- 30 8. A set according to claim 7, characterised in that said pair of opposite facing tongues (63) of the sleeve are flexible and are formed by means of longitudinal notches (66) in said longitudinal protrusions (65) of the sleeve, to be able to bend inward and outward.
9. A set according to any one of the preceding claims, characterised in that said locking means for locking the sleeve (5) in a retracted position of use comprise a

collar (11) protruding radially outward from the rear edge of the syringe body and a pair of longitudinal flexible tongues (56) formed in diametrically opposite positions in the rear part (52) of said sleeve (5), said flexible tongues (56) having respective protrusions (58) able to engage with said collar (11) to retain the syringe body.

5

10. A set according to claim 9, characterised in that said flexible tongues (56) of the sleeve have a rear part protruding rearward with respect to the rear edge of the sleeve and said operating means of the shaft comprise a circular crown (43) disposed in the rear part of the shaft (41) cooperating with said rear part of the flexible tongues (56) of the sleeve so as to generate the outward bending of said flexible tongues (56) and the disengagement of said collar (11) of the syringe body from the protrusions (58) of the flexible tongues.

11. A set according to claim 10, characterised in that the rear ends of the flexible tongues (56) and of said protrusions (58) have respective tapered inner surfaces (59, 58') able to cooperate with a complementary tapered surface (44) provided in the front part of said circular operating crown (43).

12. A set according to any one of the preceding claims, characterised in that said spring means comprise a spiral spring (7) disposed around the syringe body (1) with one end abutting against a collar (11) protruding outward from the rear part of the syringe body and the other end abutting against an annular abutment surface (55) provided inside the rear part (52) of said sleeve.

13. A disposable automatic safety syringe (100) comprising:

- a syringe body (1) hollow on the inside and open at the front and rear,
- a plunger (4) slidable inside the syringe body (1) with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger (4) being provided at the rear with a shaft (41) that can be operated manually and brought out of the syringe body through the rear end (42) thereof,
- an injection needle (2) supported by a needle-carrying support (20) engageable at the fore end (13) of the syringe body (1),

- a sleeve (5) mounted slidably over said syringe body (1) to pass from a retracted position of use of the syringe to a forward position of safety, wherein it covers said needle (2),
- spring means (7) disposed under compression between said sleeve (5) and said syringe body (1) to urge the axial movement of the sleeve (5) with respect to the syringe body,
- locking means (56, 58, 11) provided in the rear part of the sleeve (5) and in the rear part of the syringe body (1), in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of said spring means,
- operating means (44) disposed in said shaft (41) to release said locking means (56, 58), when the plunger (4) reaches the end of the injection stroke, so as to allow axial movement of the sleeve into the safety position, thanks to the action of the spring means, and
- a guide element (8; 108) able to be made integral with the syringe body (1) and comprising guide means (83) cooperating with complementary guide means (60) formed in said sleeve (5) to guide the axial movement of the sleeve (5) with respect to the syringe body.

14. A syringe according to claim 13, characterised in that said guide means of the sleeve (5) comprise a pair of longitudinal channels (60) disposed in diametrically opposite positions in the central part of said sleeve and said guide means of the guide element (8; 108) comprise a pair of teeth or nibs (83), disposed in diametrically opposite positions able to engage in a sliding coupling relationship inside the respective longitudinal channels (60).

25

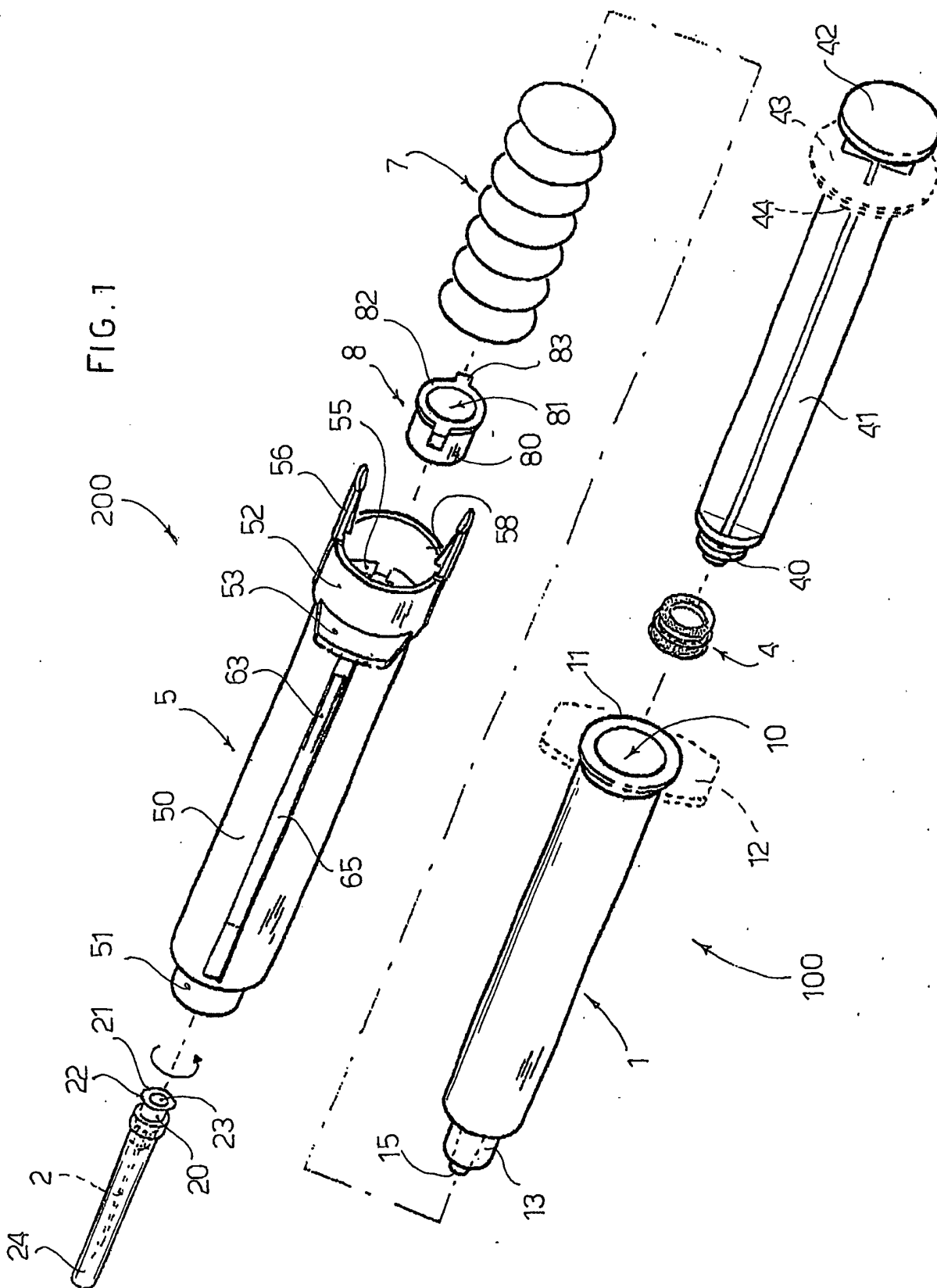
15. A syringe according to claim 13 or 14, characterised in that said guide element (8; 108) has the form of a cylindrical tang hollow on the inside, suitable to be applied on the head (13; 115) of said syringe body.

16. A syringe according to any one of claims 13 to 15, characterised in that locking means are formed in said sleeve (5) able to lock same to the syringe body (1) when it is in its extracted safety position, said locking means comprising a pair of opposing tongues (63, 67) disposed in each longitudinal channel (60) and having respective opposing abutment surfaces (64, 62) able to lock said nibs (83) of the guide element

(8; 108) integrally to the syringe body, in order to avoid axial movement of the syringe body when the sleeve is in the deployed position of safety.

17. A syringe according to any one of claims 13 to 16, characterised in that said
- 5 locking means to lock the sleeve (5) in the retracted position of use comprise a collar (11) protruding radially outward from the rear edge of the syringe body and a pair of flexible longitudinal tongues (56) formed in diametrically opposite positions in the rear part (52) of said sleeve (5), said flexible tongues (56) having respective protrusions (58) able to engage with said collar (11) to retain the syringe body and
- 10 said flexible tongues (56) having a rear part protruding rearward with respect to the rear edge of the sleeve and said operating means of the shaft comprising a circular crown (43) disposed in the rear part of the shaft (41) cooperating with said rear part of the flexible tongues (56) of the sleeve so as to generate the outward bending of said flexible tongues (56) and release of said collar (11) of the syringe body from the
- 15 protrusions (58) of the flexible tongues.

1/6



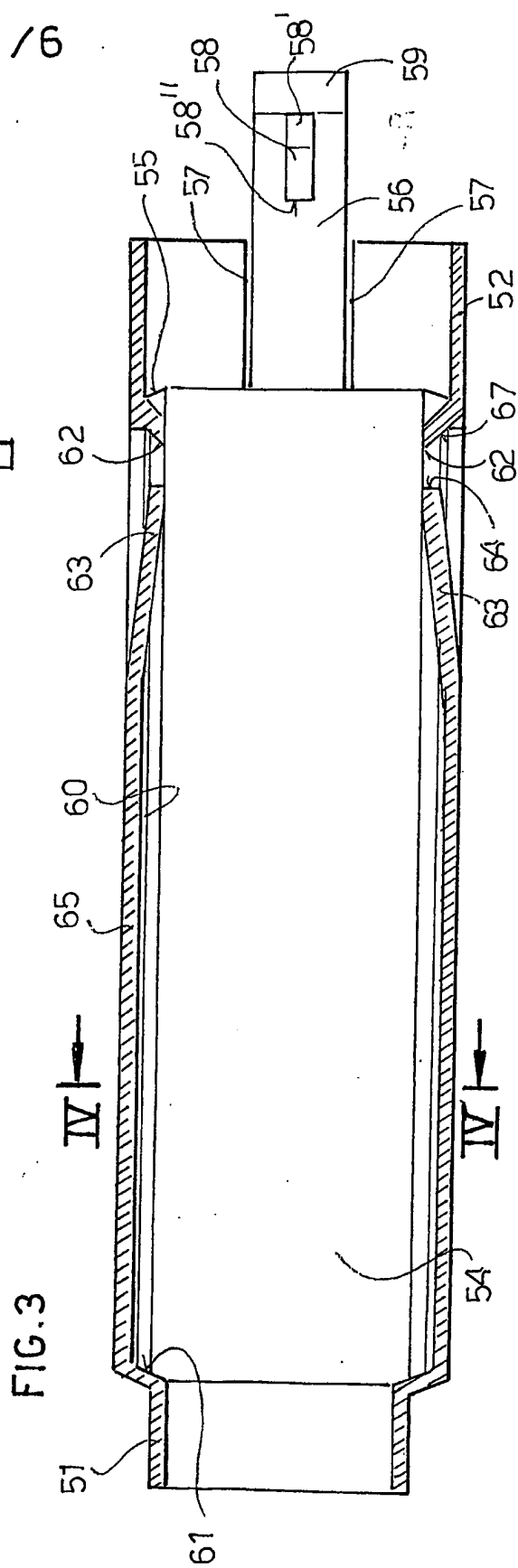
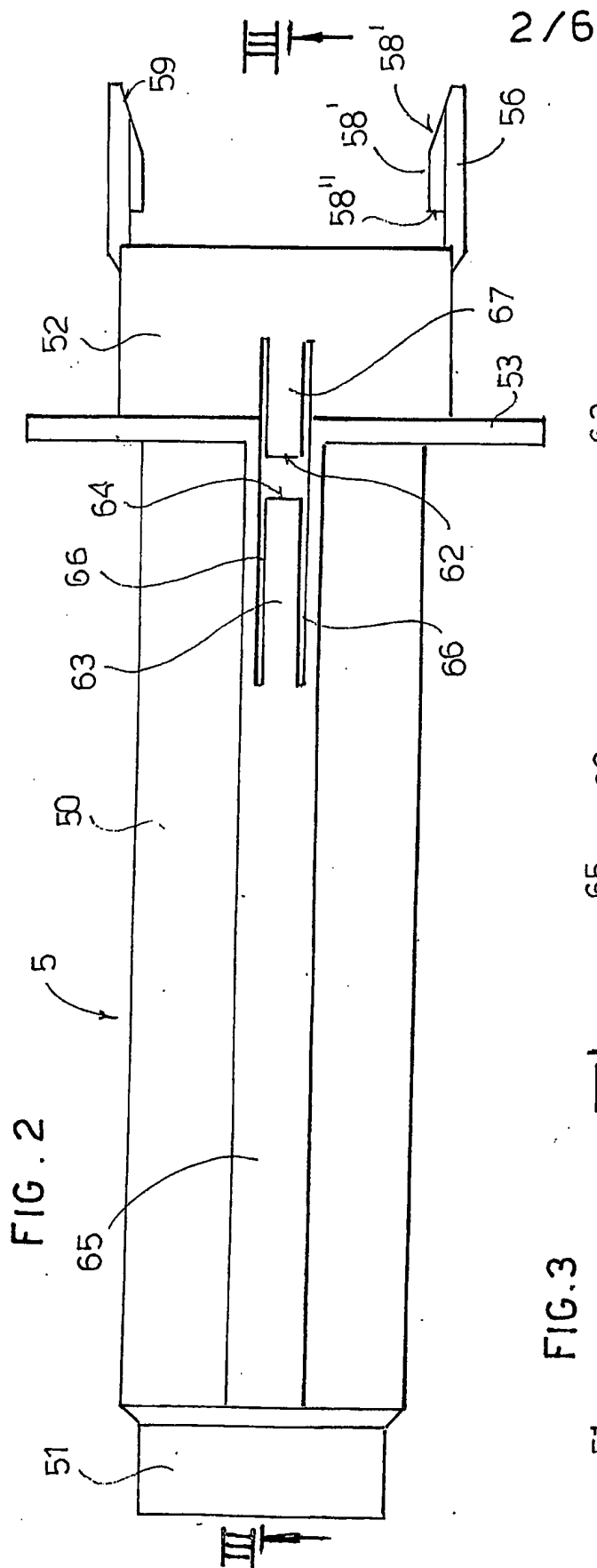
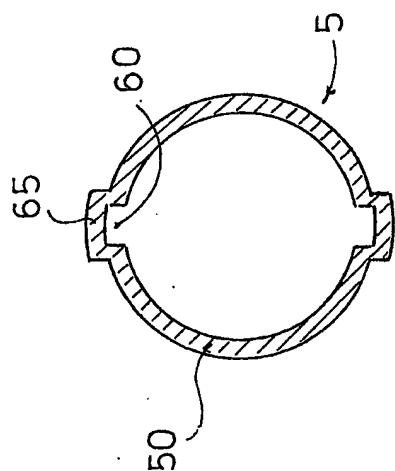


FIG. 4



3 / 6

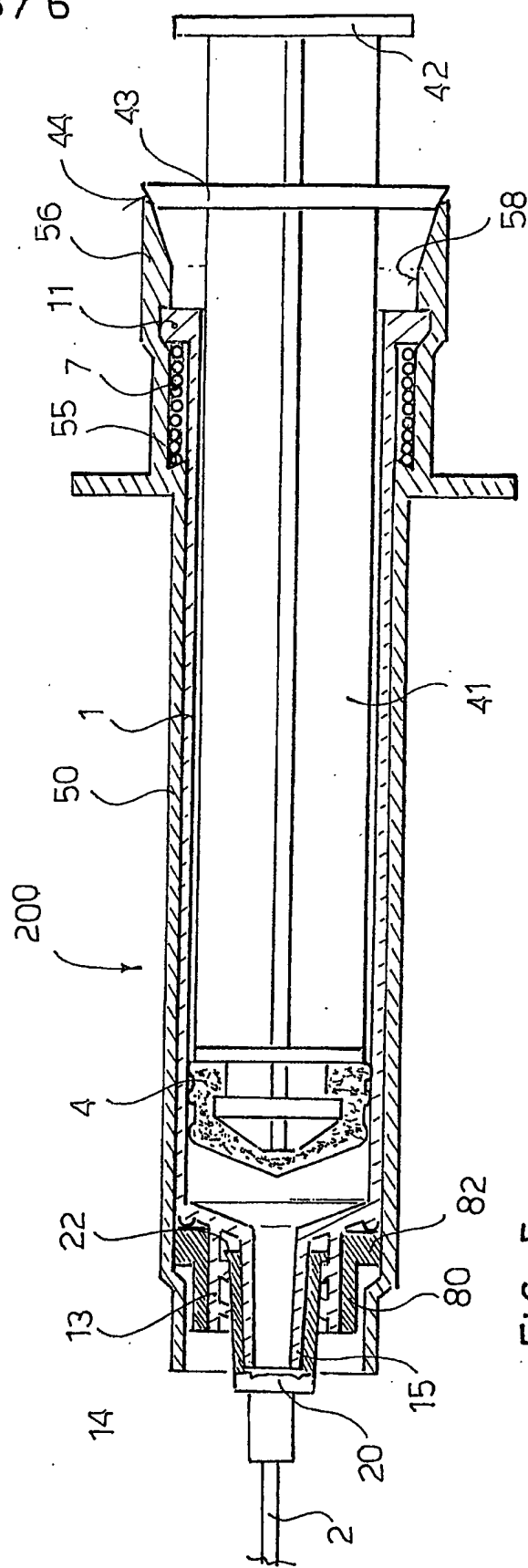
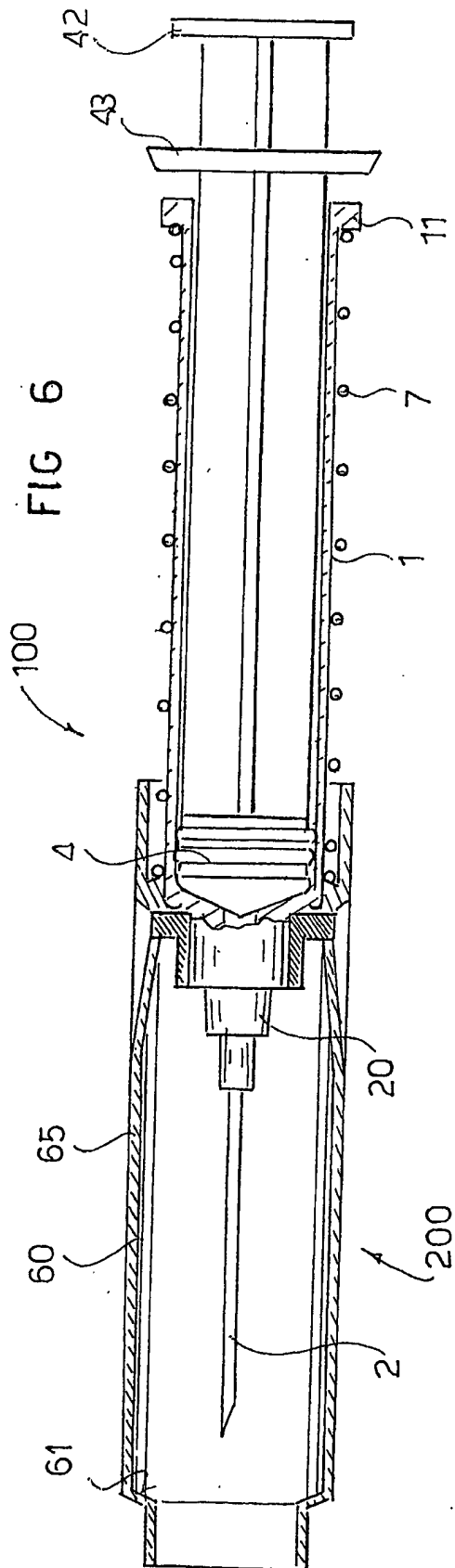
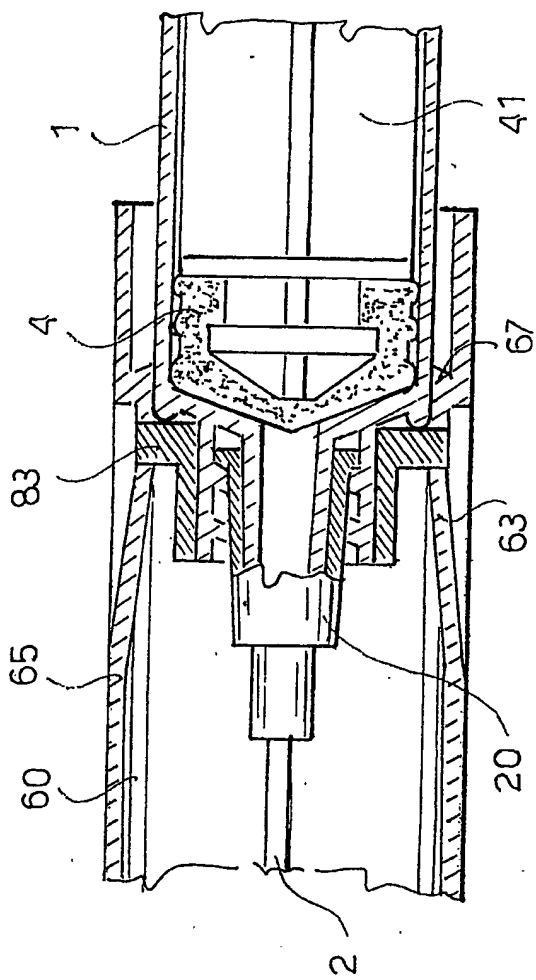


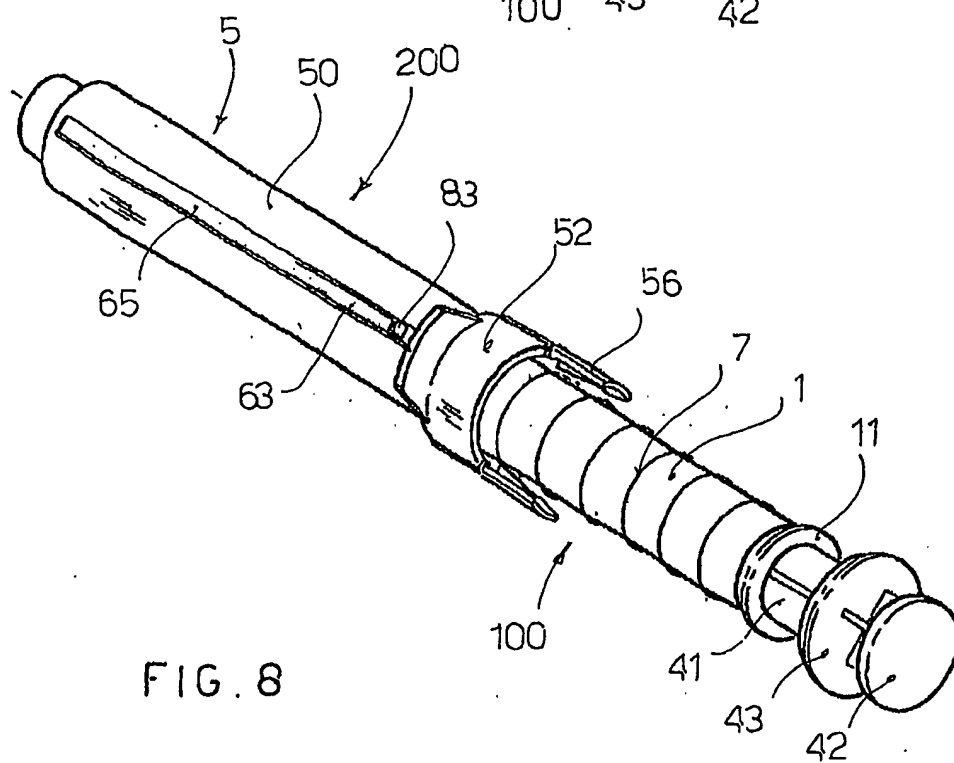
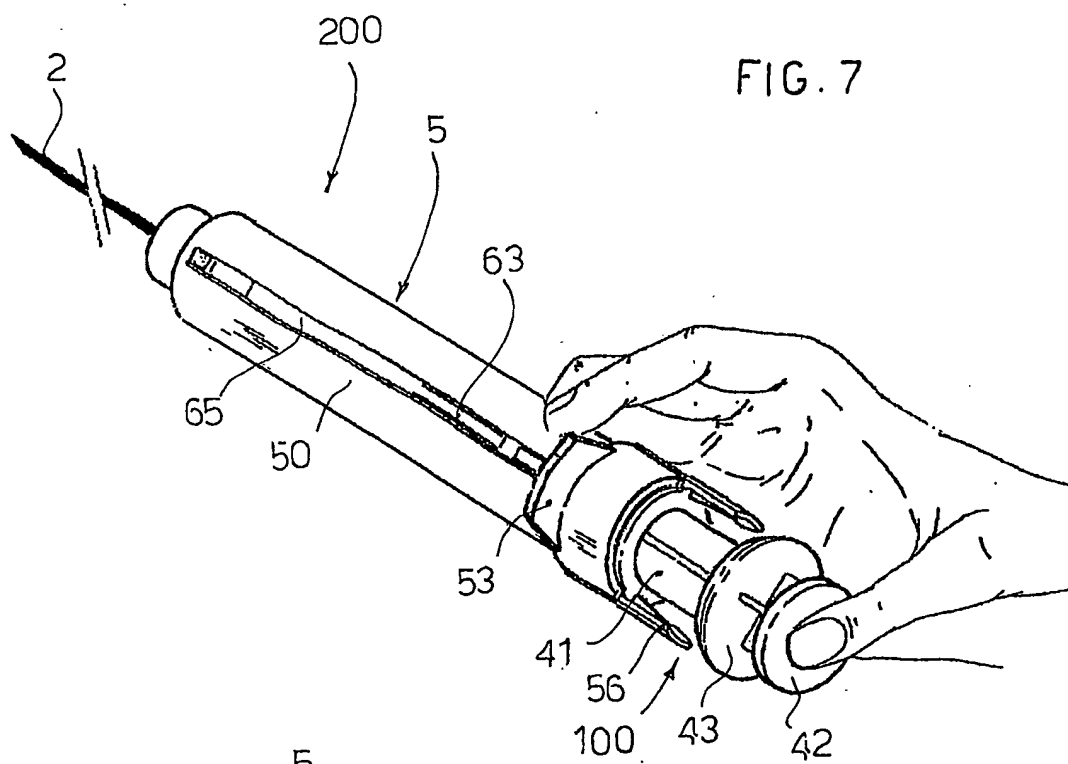
FIG. 5



4/6



5/6



6 / 6

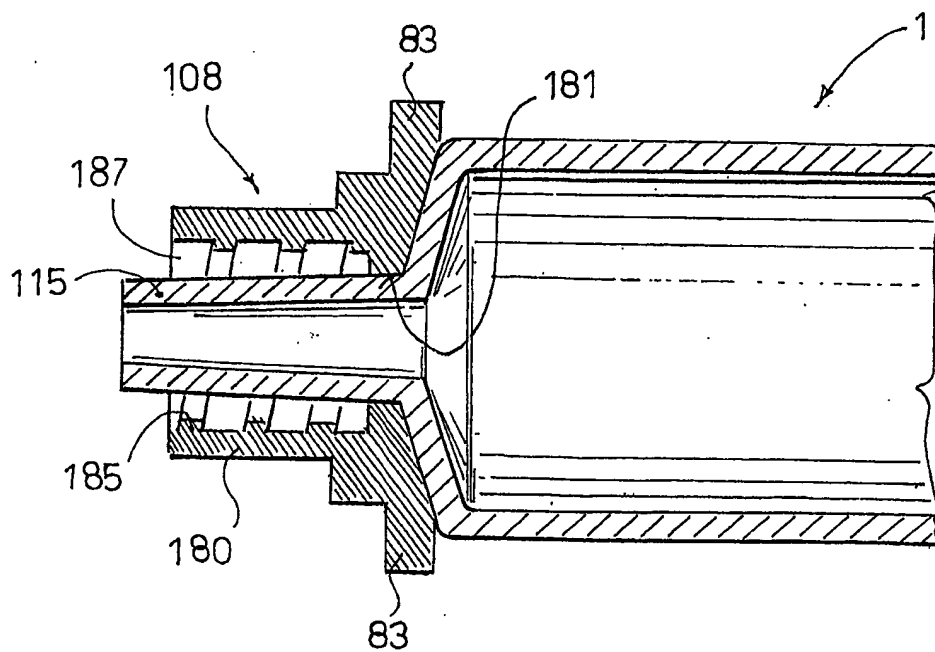
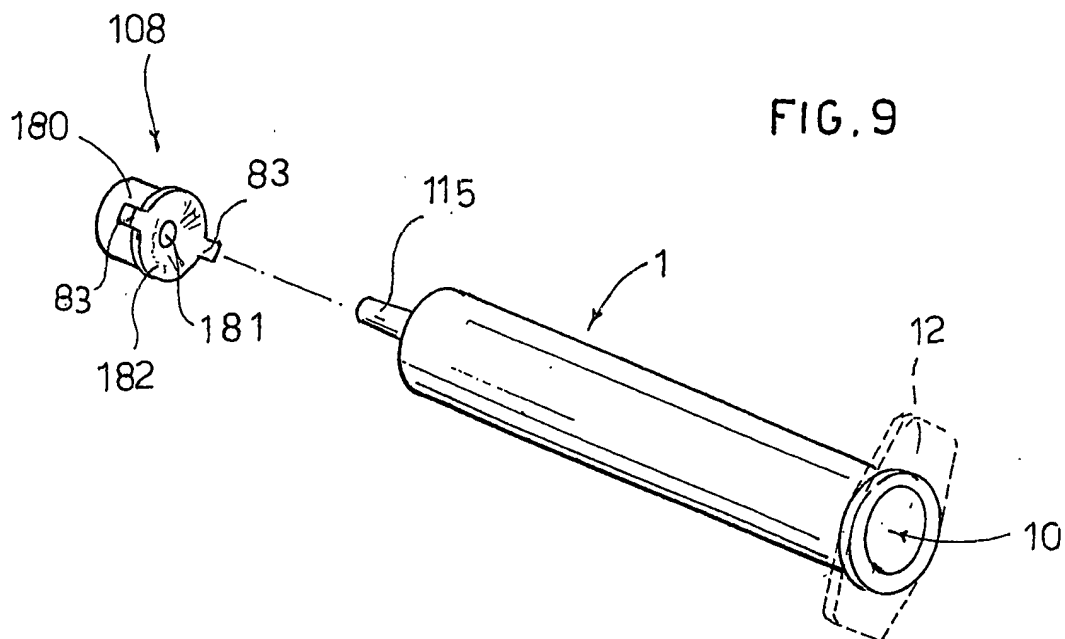


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No

PCT/IT 02/00696

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 35714 A (RIGHI NARDINO ;RESTELLI SERGIO (IT)) 20 August 1998 (1998-08-20) page 9, line 11 -page 16, line 23; figures 2-5	1,2, 5-14,16, 17
Y	---	3,4,15
Y	EP 0 506 204 A (SHERWOOD MEDICAL CO) 30 September 1992 (1992-09-30) column 5, line 23-30 column 6, line 12-33; figures 1-3	3
Y	WO 98 10816 A (DRUCE JENNIFER ;SPRINGBARRON PTY LIMITED (AU)) 19 March 1998 (1998-03-19) page 4, line 30 -page 5, line 6; figures 2,3 --- -/--	4,15

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

25 June 2003

Date of mailing of the international search report

09/07/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Rosenblatt, T

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 02/00696

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 017 329 A (HAKE LAWRENCE W) 25 January 2000 (2000-01-25) column 4, line 17-31 column 5, line 30 -column 6, line 39 column 7, line 54 -column 8, line 15 figures 1-7 -----	2-4, 15
A	WO 99 37345 A (RIGHI NARDINO ;ROSSI ROBERTO (IT); RESTELLI SERGIO (IT)) 29 July 1999 (1999-07-29) cited in the application the whole document -----	1, 13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IT 02/00696

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9835714	A	20-08-1998	IT SV970007 A1	12-08-1998
			IT SV970008 A1	12-08-1998
			AU 6719198 A	08-09-1998
			WO 9835714 A1	20-08-1998
			EP 1017436 A1	12-07-2000
EP 0506204	A	30-09-1992	US 5156599 A	20-10-1992
			US 5053018 A	01-10-1991
			AT 94076 T	15-09-1993
			EP 0506204 A2	30-09-1992
			AT 136797 T	15-05-1996
			AU 641863 B2	30-09-1993
			AU 1605592 A	09-07-1992
			AU 621127 B2	05-03-1992
			AU 3706589 A	04-01-1990
			CA 1324937 C	07-12-1993
			DE 68908975 D1	14-10-1993
			DE 68908975 T2	31-03-1994
			DE 68926312 D1	23-05-1996
			DE 68926312 T2	19-09-1996
			DK 315489 A	29-12-1989
			EP 0350186 A1	10-01-1990
			ES 2045439 T3	16-01-1994
			ES 2085550 T3	01-06-1996
			JP 2104369 A	17-04-1990
			JP 2916779 B2	05-07-1999
			SG 27294 G	10-06-1994
			US 5169392 A	08-12-1992
			US 5312370 A	17-05-1994
			US 5403287 A	04-04-1995
			US 5522812 A	04-06-1996
			US 5088988 A	18-02-1992
			US 5147326 A	15-09-1992
			US 5127910 A	07-07-1992
			US 5160326 A	03-11-1992
			US 5217437 A	08-06-1993
WO 9810816	A	19-03-1998	AU 4105797 A	02-04-1998
			WO 9810816 A1	19-03-1998
US 6017329	A	25-01-2000	US 5256153 A	26-10-1993
			US 5019051 A	28-05-1991
			AT 163360 T	15-03-1998
			BR 9206037 A	02-08-1994
			CA 2109713 A1	26-11-1992
			DE 69224521 D1	02-04-1998
			DE 69224521 T2	18-06-1998
			EP 0585391 A1	09-03-1994
			JP 6507804 T	08-09-1994
			MX 9202429 A1	01-11-1992
			US 5314414 A	24-05-1994
			WO 9220390 A1	26-11-1992
			US 5843041 A	01-12-1998
			CA 2009560 A1	02-09-1990
			US 5141500 A	25-08-1992
WO 9937345	A	29-07-1999	IT SV980003 A1	20-07-1999
			AU 741678 B2	06-12-2001

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IT 02/00696

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9937345	A	AU 2517899 A	09-08-1999
		BR 9907718 A	18-12-2001
		CA 2318594 A1	29-07-1999
		CN 1288391 T	21-03-2001
		WO 9937345 A1	29-07-1999
		EP 1049503 A1	08-11-2000
		JP 2002500934 T	15-01-2002
		US 6419658 B1	16-07-2002